

(19)



Europäisches Patentamt

European Patent Office

Office européen des brevets



(11)

EP 1 612 554 A1

(12)

## EUROPEAN PATENT APPLICATION

(43) Date of publication:

04.01.2006 Bulletin 2006/01

(51) Int Cl.:

G01N 33/487 (2006.01)

C12Q 1/00 (2006.01)

B01L 11/00 (2006.01)

A61B 5/145 (2006.01)

(21) Application number: 05254021.8

(22) Date of filing: 28.06.2005

(84) Designated Contracting States:

AT BE BG CH CY CZ DE DK EE ES FI FR GB GR  
HU IE IS IT LI LT LU MC NL PL PT RO SE SI SK TR

Designated Extension States:

AL BA HR LV MK YU

(30) Priority: 29.06.2004 US 881774

(71) Applicant: LifeScan, Inc.

Milpitas, CA 95035 (US)

(72) Inventor: Allen, John J.

Mendota Heights

Minnesota 55118 (US)

(74) Representative: Mercer, Christopher Paul et al

Carpmaels & Ransford,

43-45 Bloomsbury Square

London WC1A 2RA (GB)

### (54) A method of preventing reuse of a test strip

(57) The present invention is a method of preventing the reuse of test strips for measuring an analyte or indicator such as glucose in a physiological fluid such as blood, interstitial fluid, or urine, said method comprising the steps of: inserting a test strip into a meter; detecting electrical continuity between a first electrical contact zone and a second electrical contact zone on said test strip and initiating a measurement sequence when said electrical continuity is present;

applying a physiological sample to said disposable test strip;  
measuring a signal from said test strip that corresponds to an analyte concentration; and  
applying a voltage between said first electrical contact zone and said second electrical contact zone wherein said voltage is sufficient to destroy a frangible link between said first electrical contact and said second electrical contact.

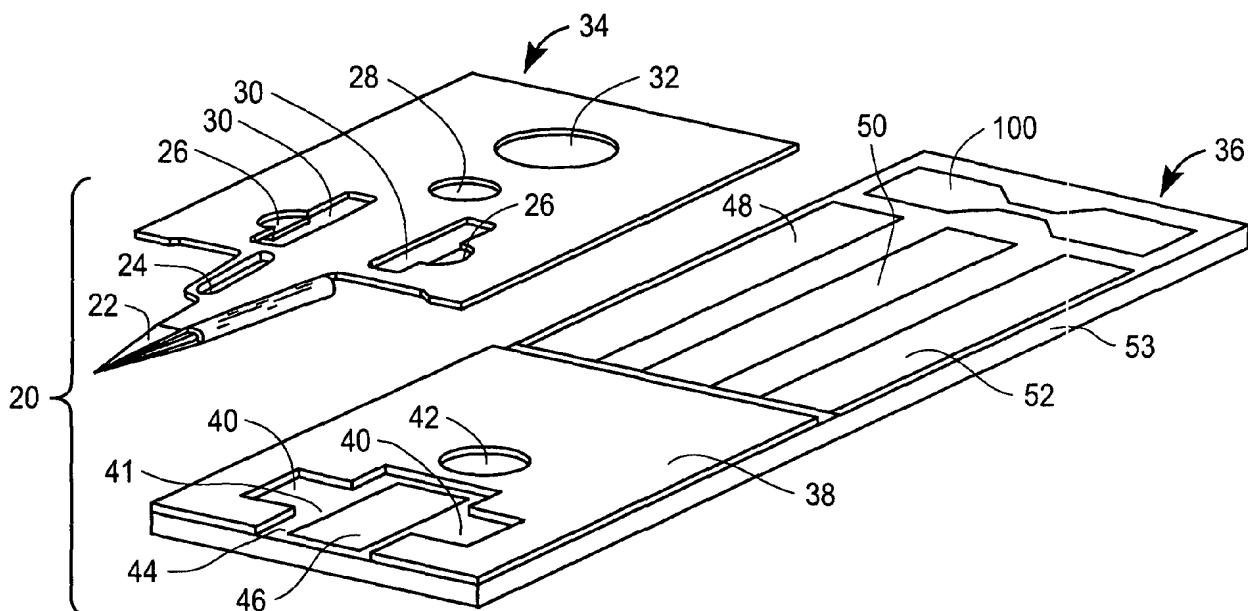


FIG. 1

**Description****CROSS-REFERENCE**

**[0001]** This application is related to co-pending international application serial number PCT/GB01/05634, filed on December 19, 2001, entitled "Analyte Measurement" (published as WO 02/49507) which is hereby incorporated herein by reference.

**BACKGROUND OF THE INVENTION**

**[0002]** The present invention relates, in general, to test strips for measuring an analyte or indicator such as glucose in a physiological fluid such as blood, interstitial fluid, or urine. More particularly, the present invention relates to a method of preventing the reuse of such test strips.

**[0003]** The present invention is a method of preventing reuse of test strips for measuring an analyte or indicator such as glucose in a physiological fluid such as blood, interstitial fluid, or urine. The present invention also relates to a method of preventing reuse of test strips incorporating an integrated lance such as a needle, blade, or other sharp or skin puncturing device. Certain types of medical devices such as, for example, glucose test strips were intended to be tested only once and then disposed. This requirement is often needed because the reagent chemistry in many test strips is not suitable for measuring glucose a second time. However, it is possible that some user will accidentally test a previously used test strip. This could potentially become a problem if the glucose meter attempts to make a glucose measurement and outputs a result. Therefore, it is desirable that a single use test strip and meter have a prescribed method for preventing a previously tested test strip from being reused.

**[0004]** Recently, micro-needles (e.g. lances) and test strips (e.g., electrochemical-based and photometric-based biosensors) have been integrated into a single medical device. These integrated medical devices can be employed, along with an associated meter, to monitor various analytes, including glucose. Depending on the situation, biosensors can be designed to monitor analytes in an episodic single-use format, semi-continuous format, or continuous format. The integration of a micro-needle and biosensor simplifies a monitoring procedure by eliminating the need for a user to coordinate the extraction of a sample from a sample site with the subsequent transfer of that sample to a biosensor. This simplification, in combination with a small micro-needle and a small sample volume, also reduces pain.

**[0005]** For the case in which test strips are integrated with a lancing device, there is an added potential problem in that the re-use of test strips may result in cross-contamination. The lancing portion of the integrated device may have blood remaining on it which could infect a second user who might accidentally use the test strip. Therefore, it is also desirable that the meter and test strip sys-

tem have a method which prevents a previously used test strip from launching the lance mechanism.

**SUMMARY OF THE INVENTION**

**[0006]** The present invention is directed to a method of preventing the reuse of a test strip in an analyte measuring system wherein the method includes the steps of inserting a test strip into a meter; detecting an electrical continuity with said meter between a first electrical contact zone and a second electrical contact zone; applying a physiological sample to the disposable test strip; measuring a signal from the test strip that corresponds to an analyte concentration; and applying a voltage between said first and second electrical contact zone sufficient to destroy a frangible link between said first electrical contact and said second electrical contact.

**[0007]** In a further embodiment of the present invention, a method of preventing the reuse of the test strips further includes the steps of: providing a fuse zone between said first and second electrical contact zones, wherein said fuse zone has a higher resistance than the first and second electrical contact zones.

**[0008]** In a further embodiment of a method according to the present invention, the analyte measuring system wherein the conductive trace has a positive temperature coefficient of resistance, the conductive trace being a material chosen from a group consisting of carbon, silver, platinum, palladium, gold, Ir, Pt, tungsten, copper, and aluminum. In a further embodiment of the present invention, the fuse zone melts, forming an open circuit, when the predetermined voltage is applied between said first electrical contact and said second electrical contact wherever the predetermined voltage may range from about 1.5 volts to about 30 volts.

**[0009]** In further embodiments of the method of the present invention, the analyte measuring system may also include one or more of the following elements, an integrated lance; a working electrode and a reference electrode; a reagent layer is disposed on at least a portion of said working electrode wherein said reagent layer may be a redox mediator and a redox enzyme; and a silica filler.

**45 BRIEF DESCRIPTION OF THE DRAWINGS**

**[0010]** The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which principles of the invention are utilized, and the accompanying drawings of which:

**[0011]** Figure 1 is a top exploded perspective view of a test strip embodiment having an integrated lance and a fuse;

**[0012]** Figure 2A is a partial plane view of a fuse which has a continuous conductive path;

**[0013]** Figure 2B is a partial plane view of a fuse which has a discontinuous conductive path;

**[0014]** Figure 3 is a bottom perspective view of a top layer of the test strip embodiment having an integrated lance;

**[0015]** Figure 4 is a flow chart illustrating a method of preventing reuse according to the present invention;

**[0016]** Figure 5 is a simplified schematic of a meter adapted for establishing electrical contact with a test strip of the present invention; and

**[0017]** Figure 6 is a simplified schematic of a meter interfaced with a test strip of the present invention.

#### DETAILED DESCRIPTION OF ILLUSTRATIVE EMBODIMENTS OF THE INVENTION

**[0018]** Figure 1 is a top perspective view of a test strip 20 according to the present invention. In this embodiment test strip 20 includes a first portion, in this case a top layer 34; a fixing mechanism, in this case an adhesive layer 38; and a second portion, in this case a bottom layer 36. In this example embodiment, bottom layer 36 includes a conductive layer which is deposited on a substrate 53. The conductive layer includes a first working electrode 48, a second working electrode 50, a reference electrode 52, and a frangible mechanism such as a fuse 100 here in the form of a frangible conductive pad. First working electrode 48, second working electrode 50, and reference electrode 52 may be in the form of a conductive pad. Top layer 34 includes the roof of sample receiving chamber 41. In an embodiment of the present invention, top layer 34 further includes an integrated lance 22, a stiffening rib 24, side embossment spacers 26, vents 30, a distal embossment spacer 28, and a registration hole 32 as shown in Figure 2. It should be noted that top layer 34 which incorporates integrated lance 22 may also known as a lancing first portion.

**[0019]** Test strip 20, which may be rectangular or another shape, is constructed by using a fixing mechanism such as adhesive layer 38 to attach top layer 34 to bottom layer 36. In an embodiment of the invention, test strip 20 may have an approximate width of 0.22 inches (i.e. 5.6 mm) and an approximate length of 0.55 inches (i.e. 14 mm). In the embodiment of Figure 1, the proximal end of test strip 20 includes fuse 100, while the distal end of test strip 20 includes integrated lance 22.

**[0020]** Test strip 20 further includes a sample receiving chamber 41 which is formed by the aggregate lamination of bottom layer 36, adhesive layer 38, and top layer 34 which represent the respective floor, wall, and roof of sample receiving chamber 41. Test strip 20 may be, for example, a glucose test strip which uses electrochemistry to measure the amount of glucose in a bodily fluid, such as, for example, blood or interstitial fluid. Alternatively or additionally, test strip 20 may be, for example, a coagulation sensor which measures a physical characteristic of a body fluid such as viscosity, capacitance, resistance, and the like.

**[0021]** The use of integrated lance 22 in test strip 20 makes testing simpler by eliminating the step of manually transferring sample into sample receiving chamber 41. Many previous sensor systems require a lancing step using a dedicated lancing device followed by the manual manipulation of the test strip so that it can be dosed with sample. The use of integrated lance 22 allows fluid to seamlessly flow from the wound to sample receiving chamber 41 without removing integrated lance 22.

**[0022]** In an embodiment of the present invention, fuse 100 is deposited on substrate 53 by a process such as, for example, screen printing, sputtering, evaporation, electroless plating, ink jetting, sublimation, chemical vapor deposition, and the like. The geometry of fuse 100 may be formed by using a screen which selectively allows conductive material to pass through in a defined pattern such as the one shown in Figure 2. Suitable materials which may be used for fuse 100 are carbon, silver, platinum, palladium, gold, Ir, Pt, tungsten, copper, aluminum, and the like. In an embodiment of this invention, fuse 100 may be deposited during the same print cycle that deposes first working electrode 48, second working electrode 50, and reference electrode 52, and thus, shows that the process of making fuse 100 may be simple and inexpensive to implement.

**[0023]** As shown in Figure 1, fuse 100 is located on the proximal end of test strip 20 which is the end farthest away from integrated lance 22. Fuse 100 includes a first electrical contact zone 101, a second electrical contact zone 102, and a fuse zone 103. First electrical contact zone 101 and second electrical contact zone both have a width W1 and are positioned such that they can electrically interface with a meter which can apply a voltage therebetween. In an embodiment of this invention, fuse zone 103 may have a width W2 which is less than W1. In addition, fuse zone 103 is positioned in between first electrical contact zone 101 and second electrical contact zone. Fuse 100 may have a generally rectangular shape with a narrower or waisted width W2 which corresponds to fuse zone 103. Fuse zone 103 is designed to have a higher resistance than first electrical contact zone 101 and second electrical contact zone 102 so that fuse zone 103 will blow or ablate when a certain voltage is applied across first electrical contact zone 101 and second electrical contact zone 102. In an embodiment of the present invention, fuse zone 103 may have a resistance ranging from about 0.5 ohms to about 1000 ohms. Because fuse zone 103 has a higher resistance than first electrical contact zone 101 and second electrical contact zone 102, when an appropriate voltage is applied, fuse zone 103 will heat up and eventually melt, forming an open circuit. **[0024]** As part of bottom layer 36, first working electrode 48, second working electrode pad 50, and reference electrode 52 are deposited on substrate 53. Similar to fuse 100, first working electrode 48, second working electrode 50, and reference electrode 52 may be deposited using one of the previously mentioned techniques described for fuse 100 and indeed may be manufactured

or deposited at the same time. The geometry of first working electrode 48, second working electrode 50, and reference electrode 52 may be formed by using a screen which selectively allows conductive material to pass through in a defined pattern. Suitable materials which may be used for first working electrode 48, second working electrode 50, and reference electrode 52 are Au, Pd, Ir, Pt, Rh, silver, silver chloride, stainless steel, doped tin oxide, carbon, and the like. Possible embodiments of the electrode geometry suitable for use with the subject invention include those described in U.S. Patent Nos. 6,716,577; 6,620,310; 6,558,528; 6,475,372; 6,193,873; 5,708,247; 5,951,836; 6,241,862; 6,284,125; and 6,444,115, and International Patent Application Publications WO/0167099; WO/0173124; WO/0173109; and WO/0206806, the disclosures of which are herein incorporated by reference.

**[0025]** As part of bottom layer 36, substrate 53 may be an electrically insulating material such as plastic, glass, ceramic, and the like. In a preferred embodiment of this invention, substrate 53 may be a plastic such as, for example, nylon, polyester, polycarbonate, polyimide, polyvinylchloride, polyethylene, polypropylene, and PETG. In an embodiment of the invention, the material used for substrate 53 may be a polyester material (trade name Melinex ® ST328) which is manufactured by DuPont Teijin Films.

**[0026]** As part of the bottom layer 36, insulation layer 44 may be printed or disposed over a portion of the conductive layer in order to define the electrode area which is wetted by a liquid sample. In an embodiment of this invention insulation layer 44 may be printed by using one of the aforementioned techniques described for fuse 100. In a preferred embodiment of this invention, insulation layer 44 may be printed by using screen printing techniques in either a flat bed process or in a continuous web process. A suitable material which may be used for insulation layer 44 is Ercon E6110-116 Jet Black Insulayer Ink which may be purchased from Ercon, Inc. It should be appreciated that to one skilled in the art that several different types of insulating material could be suitable for use in the described invention. In an embodiment of this invention, insulation layer 44 may have a height between 1 and 100 microns, more favorably between 5 and 25 microns, and yet even more favorably at about 5 microns.

**[0027]** As part of the bottom layer 36, reagent layer 46 may be printed by using one of the aforementioned techniques described for fuse 100. In a preferred embodiment of this invention, reagent layer 46 may be printed by using screen printing techniques. A non-limiting example of a suitable reagent or enzyme ink for use in the present invention can be found in issued US patents 5,708,247 and 6,046,051; published international applications WO01/67099 and WO01/73124. In an embodiment of this invention where test strip 20 is a glucose sensor, reagent layer 46 may comprise a redox enzyme and a redox mediator. Examples of redox enzymes may include glucose oxidase, glucose dehydrogenase using either a

methoxatin co-factor, or a nicotinamide adenine dinucleotide co-factor. Examples of redox mediators may include ferricyanide, phenazine ethosulphate, phenazine methosulfate, pheylenediamine, 1-methoxy-phenazine methosulfate, 2,6-dimethyl-1, 4-benzoquinone, 2,5-dichloro-1,4-benzoquinone, phenathiazine derivatives, phenoxyazine derivatives, metalloporphyrin derivatives, phthalocyanine derivatives, viologen derivatives, ferrocene derivatives, osmium bipyridyl complexes, ruthenium complexes and the like. It should be appreciated that one skilled in the art that variations of the previously described enzyme ink could be suitable for use in the described invention. In an embodiment of this invention, reagent layer 46 may have a height between 1 to 100 microns, and more favorably between 5 to 25 microns.

**[0028]** In an embodiment of the present invention, adhesive layer 38 includes at least portion of the walls of a sample receiving chamber 41. Adhesive layer 38 may be printed or disposed on top of a portion of insulation layer 20 and/or a portion of reagent layer 46 to at least partially form a sample receiving chamber 41 within test strip 20. Examples of methods to print adhesive layer 38 may be screen printing, gravure, and slot coating. In other embodiments, adhesive layer 38 may be a double sided pressure sensitive adhesive, a UV cured adhesive, heat activated adhesive, or a thermosetting plastic. As a non-limiting example, adhesive layer 38 may be formed by screen printing a pressure sensitive adhesive such as, for example, a water based acrylic copolymer pressure sensitive adhesive which is commercially available from Tape Specialties LTD in Tring, Herts, United Kingdom as part #A6435.

**[0029]** In an embodiment of this invention, the height of adhesive layer 38 may be between 4 and 140 microns. The minimal value for the adhesive height is bounded by the height of reagent layer 46 because it would be undesirable for top layer 34 to physically contact reagent layer 46 and result in possible damage to reagent layer 46. The maximum value of the adhesive height is bounded by the desire to reduce the overall sample volume of test strip 20. Other factors which may influence the selected adhesive height may be the desire to maintain conditions for semi-infinite diffusion in regards to the mediator oxidation (i.e. concentration of redox mediator which is sufficiently far from the electrodes are unperturbed by electrochemical reactions).

**[0030]** In an embodiment of this invention, adhesive layer 38 further includes a side clearance area 40 and a distal clearance area 42. The clearance areas within the adhesive may be used to provide an area in which side embossment spacer 26 can interface with insulation layer 44 in such a manner that top layer 34 forms the roof of sample receiving chamber 41. Adhesive layer 38 should have at least about a slightly greater height than side embossment spacers 26 and distal embossment spacer 28 so that the embossment spacers provide a mechanical stop to limit the compression of the adhesive height between the top layer 34 and bottom layer 36. Therefore,

the use of embossment spacers or other mechanical protrusions help control the sample chamber height when using either heat activated adhesive or thermosetting plastic.

**[0031]** Figure 3 is a bottom perspective view of top layer 34 which illustrates the morphology of integrated lance 22, stiffening rib 24, side embossment spacer 26, and distal embossment spacer 28 from the bottom perspective view. Top layer 34 may be, for example, a sheet of conductive material such as gold, platinum, stainless steel, silver, and palladium, or other suitable metal which has the appropriate ductility to allow embossment. For the case using stainless steel, the metal may be plated with gold, platinum, stainless steel, silver, and palladium to reduce the costs of materials. The geometry of top layer 34, side embossment spacer 26, and distal embossment spacer 28 may be formed by, for example, a stamping process which may be performed by Meier Tool and Engineering (Anoka, Minnesota). The height of side embossment spacers 26 and distal embossment spacer 28 may range from about 4 to 130 microns, more preferably between about 50 to 110 microns, and yet more preferably between about 80 to 105 microns. Vent 30 may be formed by, for example, punching through top layer 34. In an embodiment of this invention vent 30 is adjacent to side embossment spacer 26. Vent 30 may be used to partially define a portion of the wall of sample receiving chamber 41 and to facilitate the transport of bodily fluid up integrated lance 22 and into sample receiving chamber 41. Registration hole 32 may be formed during the stamping process of making top layer 34.

**[0032]** As an embodiment of the present invention, integrated lance 22 may be manufactured as an integral part of top layer 34. Integrated lance 22 may be formed in a stamping process where it has a "V" shaped open channel geometry. More details concerning the design of integrated lance 22 may be found in US provisional application serial number 60/458,242 and 60/459,465 which are incorporated by reference herein. For certain embodiments of the invention, top layer 34 may be coated with a surfactant coating or undergo a hydrophilic surface treatment to increase the capillary force of test strip 20. Non-limiting examples of surfactant coatings are Tween-80, JBR-515, Niaproof, and Tergitol. Integrated lance 22 may further include stiffening rib 24 as shown in Figure 1 and 3 which strengthens the structural integrity of integrated lance 22 and to assist with fluidic flow along integrated lance 22 to sample receiving chamber 41.

**[0033]** Figure 4 shows a flow chart 400 which describes a method of preventing the re-use of a test strip according to one embodiment of the present invention. In step 410, a meter interfaces with test strip 20 such that the meter establishes electrical contact with first working electrode 48, second working electrode 50, reference electrode 52, first electrical contact zone 101, and second electrical contact zone 102. Next, the meter performs a system check which includes probing the continuity of fuse 100 across first electrical contact 101 and second

electrical contact 102 as illustrated in step 420. In step 430, if the meter determines that fuse 100 is continuous, then meter will turn on and/or initiate a test prompting the user to launch a lancing mechanism. For the case in 5 which the fuse 100 is continuous, the meter will perform the test analyzing a physiological sample for step 440. Next, the meter will output a result of the analysis and then blow fuse 100. Figure 2B shows a partial plane view of a blown fuse which has a discontinuous zone 104. In 10 alternative embodiments to the present invention, fuse 100 can be blown at any time after step 430 because this ensures that test strip 20 will not be reused after previous exposure to a physiological sample. In an embodiment of this invention, the meter can apply a constant voltage 15 across first electrical contact zone 101 and second electrical contact zone 102 which may range from about 1.5 volts to about 30 volts. In another embodiment of this invention, the meter can apply a variable voltage for the purpose of applying a constant current across first electrical contact zone 101 and second electrical contact zone 102 which may range from about 20 microamps to 20 about 1500 microamps. In summary, this method of the present invention provides a robust strategy for ensuring that a user can only use a test strip once.

**[0034]** In addition, this method of the present invention can determine if a test strip has been previously used and prevent the user from testing a used test strip. If the meter determines that fuse 100 is discontinuous, then the meter will turn off and/or output an error message 30 indicative of defective/used test strip as shown in step 460.

**[0035]** The purpose of fuse 100 is to reduce and effectively prevent the possibility that test strip 20 is reused. An embodiment of this invention includes top layer 34 35 having an integrated lance 22. Therefore, the reuse of test strip 20 can result in cross-contamination of physiological fluid or infection to the user. Therefore, it is desirable to have fuse 100 which can allow a meter to determine if test strip 20 has already been tested. The meter 40 is designed to break fuse 100, or in some cases blow a fuse, after test strip 20 has been tested. If the meter determines that test strip 20 has been already tested (e.g. by testing that the fuse 100 is broken or the fuse is blown), the meter will either output an error message and/or prevent initiation of the test. However, if the meter determines that test strip 20 has not been tested, the meter 45 will initiate the test by either launching integrated lance 22 towards the skin or prompting the user to do so by actuating a switch.

**[0036]** Figure 5 is a simplified schematic of a meter 500 adapted for establishing electrical contact with a test strip 20 of the present invention. Meter 500 includes a strip insertion port 590, a means for measuring glucose using either one or two working electrodes, a means for determining whether test strip 20 has been previously tested with a physiological fluid, and a means for blowing fuse 100.

**[0037]** Strip insertion port 590 includes an opening or

orifice within meter 500 that allows a portion of test strip 20 to be inserted into meter 500. More specifically, the proximal end of test strip 20 may be inserted into meter 500 such that electrical contact can be established with first working electrode 48, second electrode 50, reference electrode 52, and fuse 100. Figure 6 shows an example of meter 500 forming electrical contact with the proximal end of test strip 20.

**[0038]** The means for measuring glucose includes first working electrode contact 510, second working electrode contact 520, reference electrode contact 550, first test voltage source 560, and second test voltage source 570. Meter 500 is designed such that first working electrode contact 510, second working electrode contact 520, and reference electrode contact 550 establish electrical contact with first working electrode 48, second working electrode 50, and reference electrode 52, respectively, as shown in Figure 6. When performing a glucose measurement, first test voltage source 560 may apply a first voltage E1 between first working electrode 48 and reference electrode 52. In a similar manner, second test voltage source 570 may apply a second voltage E2 between second working electrode 50 and reference electrode 52. In an embodiment of this invention, E1 and E2 may range from about -100 millivolts to about 700 millivolts, and may more preferably range about 0 millivolts to about 400 millivolts. A physiological sample is applied such that first working electrode 48, second working electrode 50, and reference electrode 52 are covered with sample. In turn, this causes reagent layer 46 to become hydrated which generates ferrocyanide in an amount proportional to the glucose present in the sample. In an embodiment of this invention, meter 500 further includes the ability to measure current which allows an oxidation current for both first working electrode 48 and second working electrode 50 to be measured after about 5 seconds from the sample application. The measured currents may then be correlated to a glucose concentration value and which is displayed on a LCD screen of meter 500.

**[0039]** The means for determining whether test strip 20 has been previously tested with a physiological fluid includes a first continuity contact 530, a second continuity contact 540, and a continuity voltage source 580. Meter 500 is designed such that first continuity contact 530 and second continuity contact 540 establish electrical contact with first electrical contact zone 101 and second electrical contact zone 102, respectively, as shown in Figure 6. When inserting test strip 20 into meter 500, continuity voltage source 580 may apply a constant voltage E3 between first electrical contact zone 101 and second electrical contact zone 102. Next meter 500 interrogates test strip 20 for an electrical continuity between first electrical contact zone and second electrical contact zone which may determined by a measured current value (as opposed to a near zero current value). If fuse 100 is determined to be continuous, then the glucose measurement is allowed to initiate. If fuse 100 is determined to not be continuous, then the glucose measurement does not in-

itialize and/or meter 500 turns off.

**[0040]** In an alternative embodiment to the present invention, continuity voltage source may apply a variable voltage such that a constant current is applied between first electrical contact zone 101 and second electrical contact zone 102. Next meter 500 interrogates test strip 20 for an electrical continuity between first electrical contact zone and second electrical contact zone which may be determined by a measured non-infinite voltage value (as opposed to an infinite voltage value).

**[0041]** The means for blowing fuse 100 includes a voltage source or current source which may be applied across first continuity contact and second continuity contact. Because meter 500 is designed such that first continuity contact 530 and second continuity contact 540 establish electrical contact with first electrical contact zone 101 and second electrical contact zone 102, a sufficiently strong voltage or current may be applied to fuse 100 such that it is blown.

**[0042]** It is an advantage of this invention in that it is more reliable than existing techniques because it identifies a used test strip as soon as the test strip is inserted into the meter. This early detection capability is especially useful for test strips having an integrated lance 22 because reuse can be a source of contamination and infection.

**[0043]** It is another advantage of this invention in that a used test strip can be identified by the meter even when the liquid sample applied to the test strip has dried. Impedance techniques for identifying a used test strip require liquid to be within the test strip.

**[0044]** It is another advantage of this invention in that a fuse can be added to the test strip at a low cost. It is a simple manufacturing step to print an additional electrode onto the test strip.

**[0045]** It is another advantage of this invention in that the circuitry required determining the continuity of a fuse is very simple and low cost.

**[0046]** While preferred embodiments of the present invention have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the invention.

**[0047]** It should be understood that various alternatives to the embodiments of the invention described herein may be employed in practicing the invention. It is intended that the following claims define the scope of the invention and that methods and structures within the scope of these claims and their equivalents be covered thereby.

## Claims

- 55 1. A method of preventing the reuse of a test strip in an analyte measuring system, said method comprising the steps of:

inserting a test strip into a meter  
detecting electrical continuity between a first  
electrical contact zone and a second electrical  
contact zone on said test strip and initiating a  
measurement sequence when said electrical  
continuity is present;  
applying a physiological sample to said dispos-  
able test strip;  
measuring a signal from said test strip that cor-  
responds to an analyte concentration; and  
applying a voltage between said first electrical  
contact zone and said second electrical contact  
zone wherein said voltage is sufficient to destroy  
a frangible link between said first electrical con-  
tact and said second electrical contact.

5

2. A method according to Claim 1 wherein said frangi-  
ble link is a fuse zone positioned between said first  
and second electrical contact zones.

10

3. A method according to Claim 2, wherein said fuse  
zone has a higher resistance than said first and sec-  
ond electrical contact zones.

20

4. A method according to Claim 1, wherein said frangi-  
ble link is a material chosen from a group consisting  
of carbon, silver, platinum, palladium, gold, Ir, Pt,  
tungsten, copper, and aluminum.

25

5. A method according to Claim 2, wherein said fuse  
zone has a positive temperature coefficient of resist-  
ance.

30

6. A method according to claim 5, wherein said fuse  
zone melts when said predetermined voltage is ap-  
plied between said first electrical contact and said  
second electrical contact.

35

7. A method according to Claim 6, wherein said prede-  
termined voltages ranges from about 1.5 volts to  
about 30 volts.

40

8. A method according to Claim 1, wherein said test  
strip further comprises an integrated lance.

45

9. A method according to Claim 1, wherein said analyte  
is glucose

10. A method according to Claim 1, wherein said test  
strip further comprises a working electrode and a  
reference electrode

50

11. A method according to Claim 10, wherein a reagent  
layer is disposed on at least a portion of said working  
electrode.

55

12. A method according to Claim 11, wherein said rea-  
gent layer comprises a redox mediator and a redox

enzyme.

13. A method according to Claim 11, wherein said rea-  
gent layer comprises a silica filler.

14. A method of preventing the reuse of a test strip, said  
method comprising the steps of:

providing a test strip comprising:

a plurality of electrical contacts;  
a sample chamber adapted to receive a  
sample of bodily fluid, wherein said  
sample chamber is connected to a fist pair  
of said electrical contacts;

a frangible link connected to a second pair of  
said electrical contacts;  
applying a predetermined voltage across said  
second pair of electrodes which said predeter-  
mined voltage is sufficient to destroy said frangi-  
ble link.

15. A method according to Claim 14, wherein said frangi-  
ble link is a fuse.

16. A method according to Claim 15, wherein said pre-  
determined voltage is in the range of between ap-  
proximately 1.5 and approximately 30 volts.

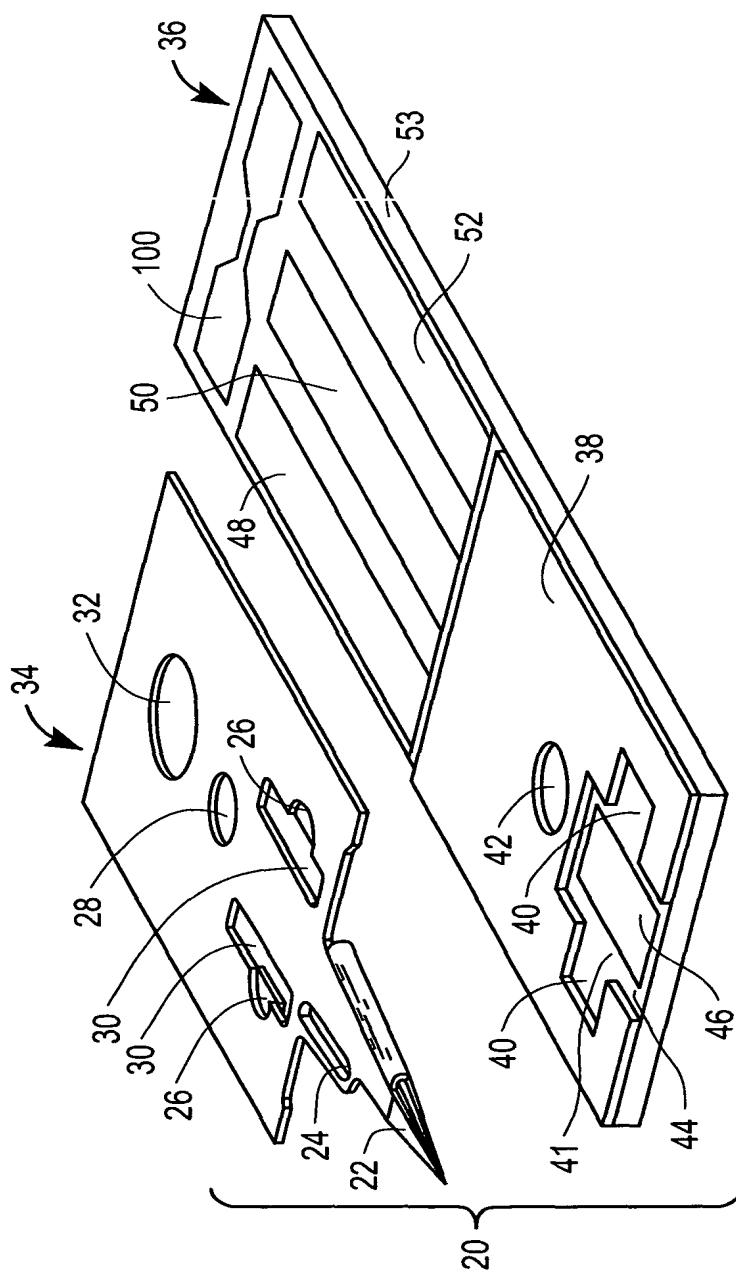


FIG. 1

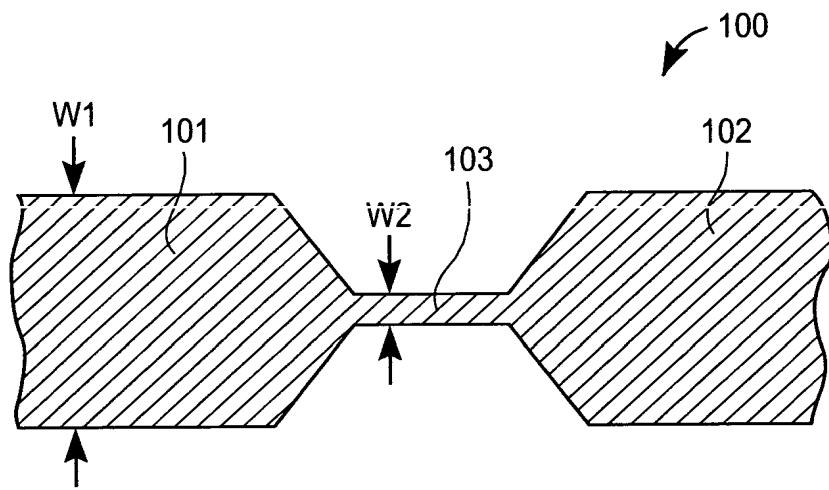


FIG. 2A

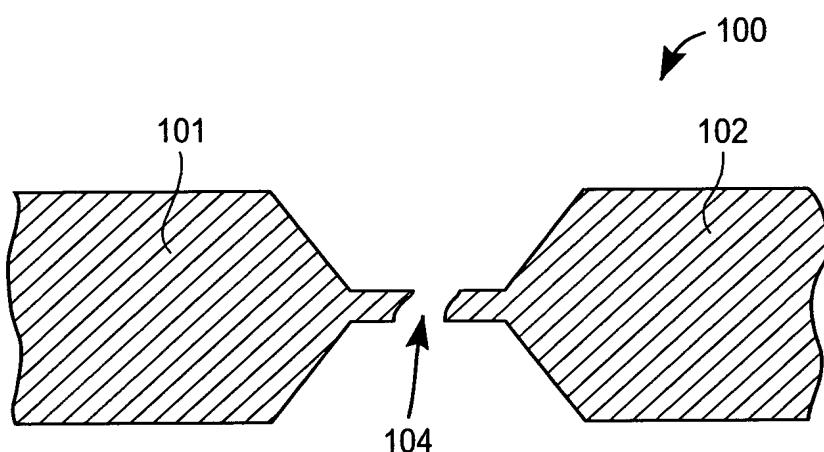


FIG. 2B

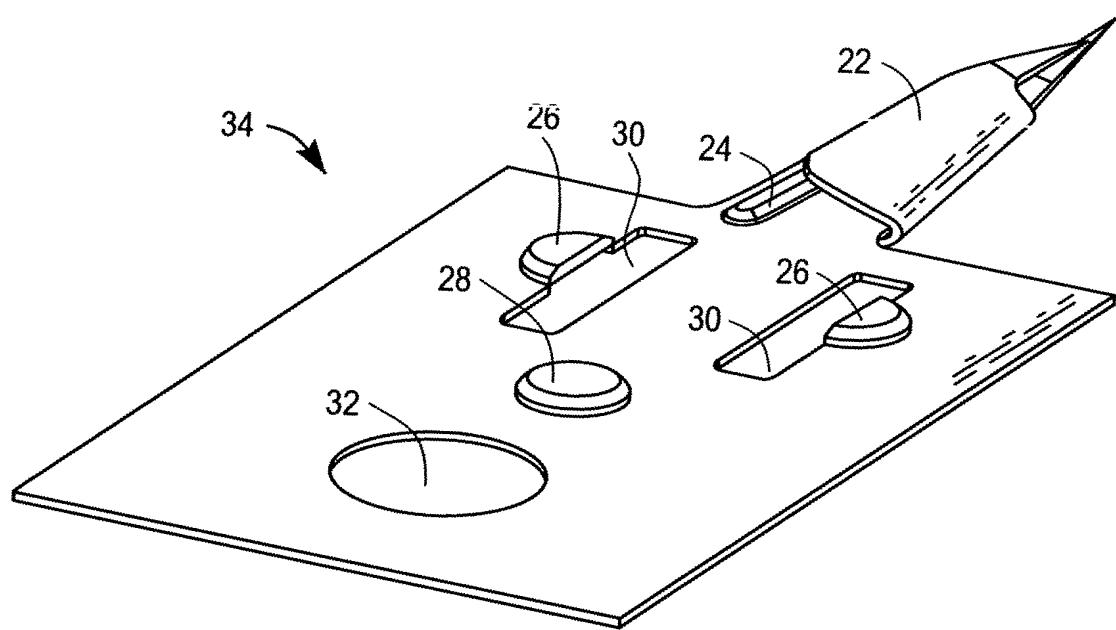


FIG. 3

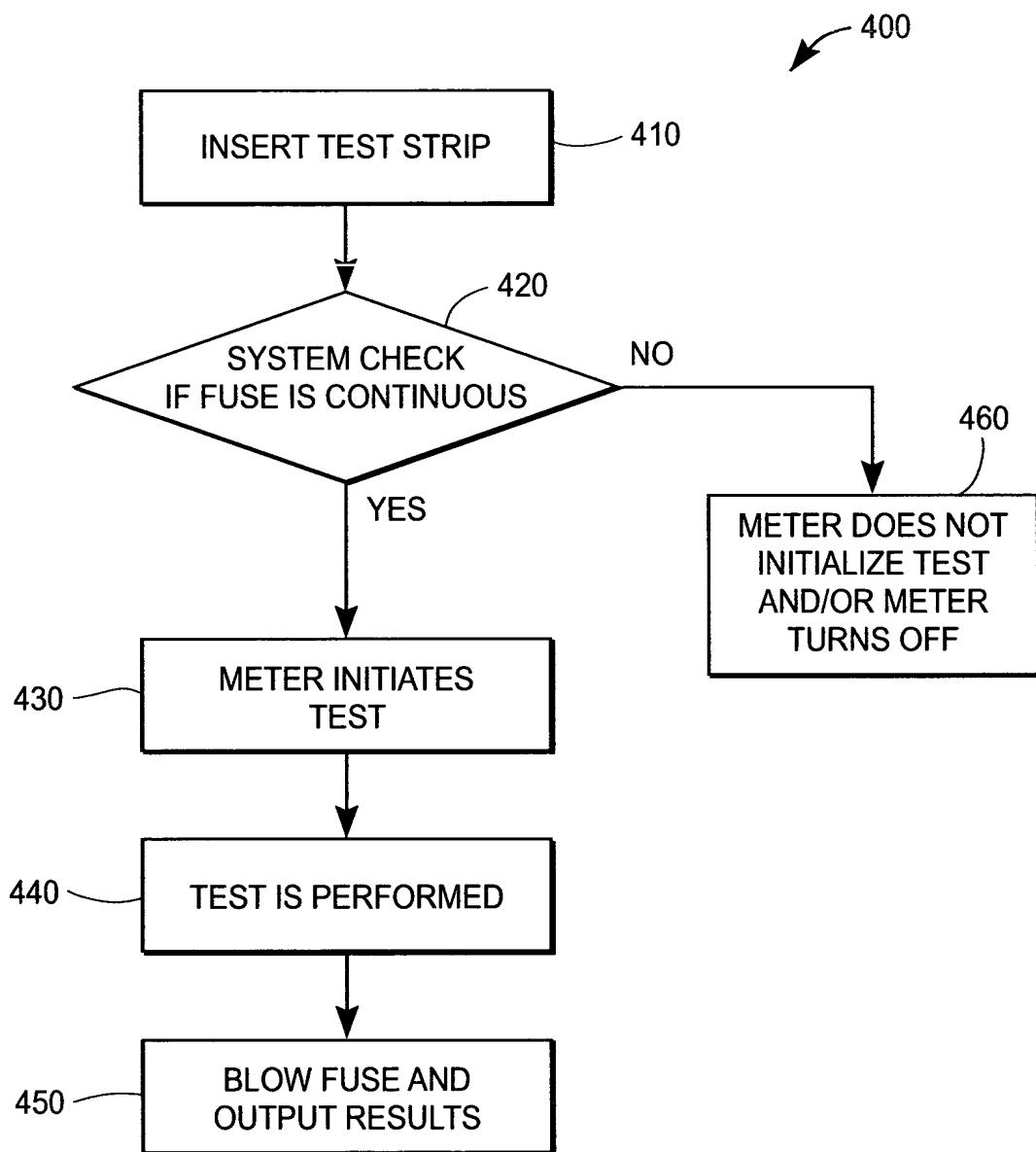


FIG. 4

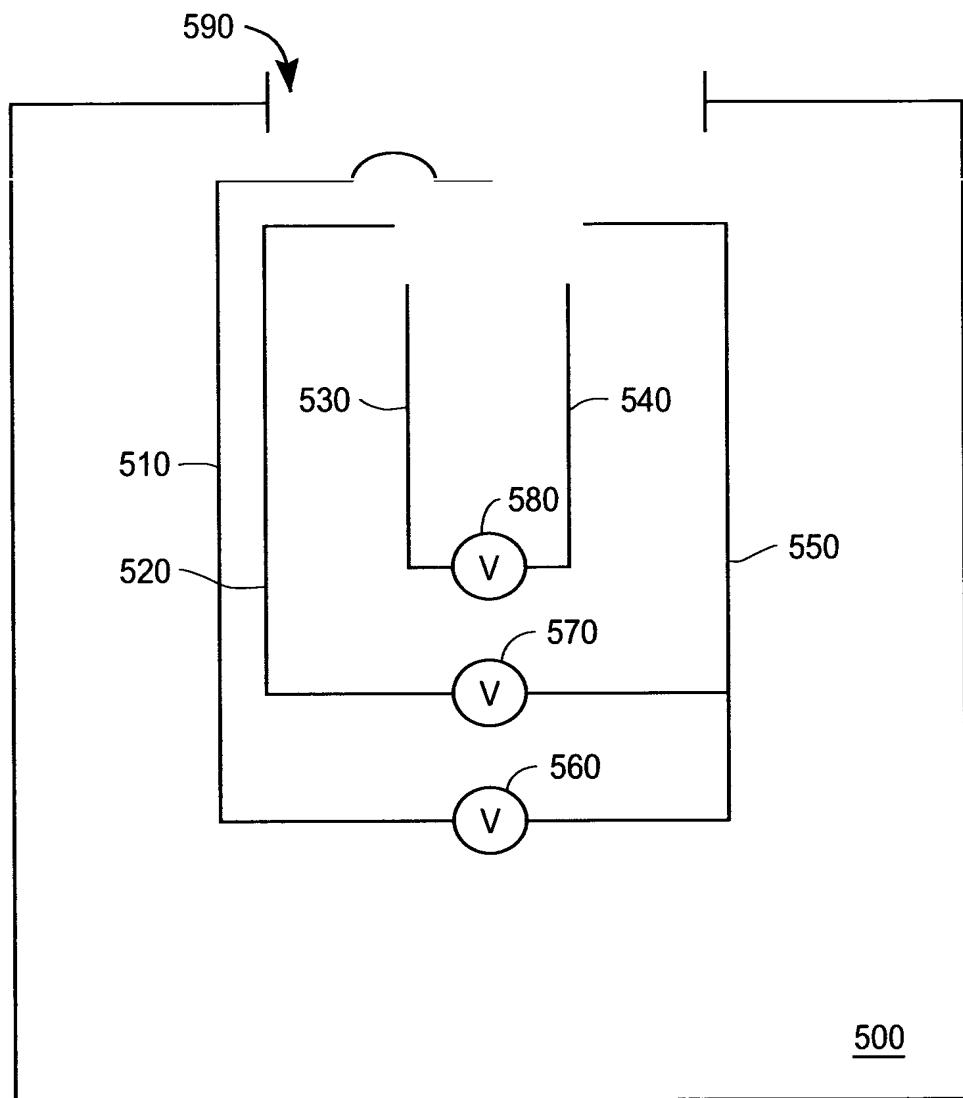


FIG. 5

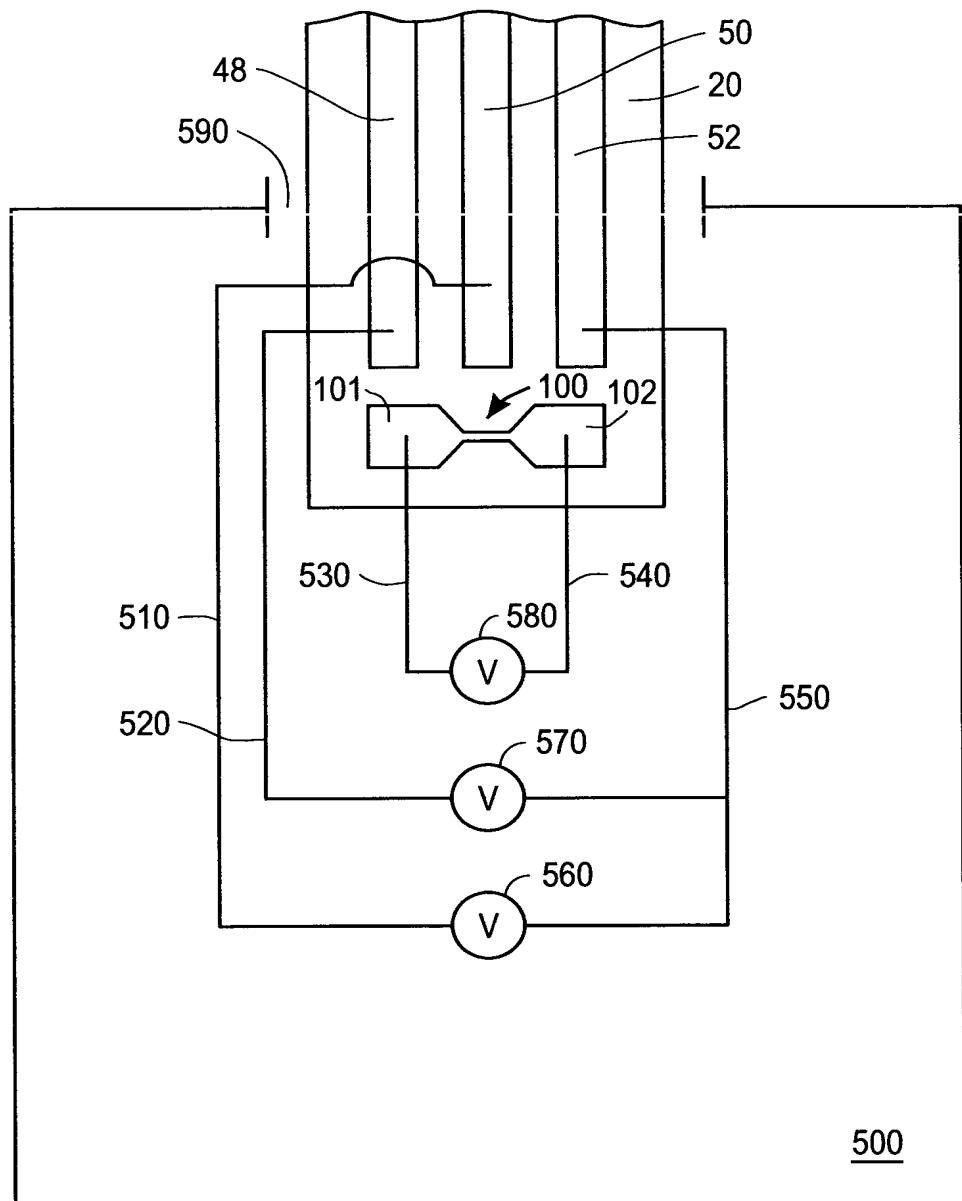


FIG. 6



European Patent  
Office

## EUROPEAN SEARCH REPORT

Application Number  
EP 05 25 4021

DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (IPC)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
X	EP 0 352 138 A (MEDISENSE, INC) 24 January 1990 (1990-01-24) * column 4, line 17 - line 64 * * column 8, line 56 - column 9, line 5; figure 2 *	1-16	G01N33/487 B01L11/00 C12Q1/00 A61B5/145
A	US 5 989 917 A (MCALLEER ET AL) 23 November 1999 (1999-11-23) * column 4, line 51 - column 5, line 2 *	1-16	
A	US 2002/177788 A1 (HODGES ALASTAIR ET AL) 28 November 2002 (2002-11-28) * paragraphs [0014], [0015]; figures *	1-16	
			TECHNICAL FIELDS SEARCHED (IPC)
			G01N B01L C12Q A61B
The present search report has been drawn up for all claims			
2	Place of search	Date of completion of the search	Examiner
	The Hague	2 November 2005	Savage, J
CATEGORY OF CITED DOCUMENTS			
X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document			
T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons ..... & : member of the same patent family, corresponding document			

**ANNEX TO THE EUROPEAN SEARCH REPORT  
ON EUROPEAN PATENT APPLICATION NO.**

EP 05 25 4021

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

02-11-2005

Patent document cited in search report		Publication date		Patent family member(s)		Publication date
EP 0352138	A	24-01-1990	AU	622196 B2		02-04-1992
			AU	3822089 A		01-02-1990
			CA	1313397 C		02-02-1993
			JP	2112752 A		25-04-1990
			US	5126034 A		30-06-1992
<hr/>						
US 5989917	A	23-11-1999	AT	215402 T		15-04-2002
			AU	712812 B2		18-11-1999
			AU	2269397 A		02-09-1997
			DE	69711604 D1		08-05-2002
			DE	69711604 T2		13-02-2003
			DK	880407 T3		01-07-2002
			EP	0880407 A1		02-12-1998
			ES	2175351 T3		16-11-2002
			PT	880407 T		30-09-2002
			WO	9729847 A1		21-08-1997
<hr/>						
US 2002177788	A1	28-11-2002	AU	4946701 A		08-10-2001
			AU	2005202586 A1		07-07-2005
			CA	2403759 A1		04-10-2001
			CN	1431884 A		23-07-2003
			CZ	20023521 A3		17-09-2003
			EP	1276412 A1		22-01-2003
			JP	2003527917 T		24-09-2003
			MX	PA02009563 A		14-05-2004
			PL	358181 A1		09-08-2004
			TW	592665 B		21-06-2004
			WO	0172220 A1		04-10-2001
			US	6612111 B1		02-09-2003
<hr/>						